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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/921,947	08/03/2001	Michel Andre Crepeau	PM 01038 (5500*86)	8375

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EXAMINER	
MITCHELL, GREGORY W	
ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/921,947	CREPEAU, MICHEL ANDRE	
	Examiner	Art Unit	
	Gregory W Mitchell	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *58-113* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *58-113* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to the remarks and amendments filed by Application on October 31, 2003. Claims 1-57 have been cancelled. Claims 58-113 have been added, are pending, and are examined herein.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 31, 2003 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 58-66, 68-73, 75-85, 87-92, 94-97, 100-101 and 105-107 are rejected under 35 U.S.C. 103(a) as being unpatentable over MVI-12 package insert (04-1998) in view of each of Lundberg, Greff (USPN 6051607) and Applicant's admission.

MVI-12 package insert discloses a water-dispersible, substantially non-combustible and substantially flammable-alcohol/mono-hydroxy alcohol free liquid composition comprising 1 mg retinol (vitamin A precursor), 10 mg dl-alpha tocopheryl

acetate (vitamin E), 0.8% polysorbate 80 (emulsifier), water, 30% propylene glycol (stabilizer), BHT and BHA (antioxidants) and gentisic acid ethanolamide (antifungal preservative). See entire disclosure.

MVI-12 does not teach a C4-C6 alkyl lactate, the preferred percentage weights and the flashpoint of at least 200° F.

Lundberg teaches ethyl lactate, sec-butyl lactate, isobutyl lactate and n-butyl lactate as known solvents for oils. Alkyl lactates are disclosed as non-ozone depleting and biodegradable solvents. Specifically, n-butyl lactate is disclosed as slightly soluble in water, miscible in alcohols, ether, many lacquer solvents, diluents and oils (page 3). Similarly, ethyl lactate is disclosed to be miscible in water, alcohols, ketones, esters, hydrocarbon, ether and oil (page 2).

Greff teaches the use of the alkyl lactate ethyl lactate as a solvent for infusions. It is taught that ethyl lactate is a desirable solvent because it provides solubility for water insoluble agents to be delivered is biocompatible and lacks undesirable toxic side effects (col. 3, line 28-col. 5, line 3).

Applicant admits on page 4 that ethyl lactate and butyl lactate are equivalent for purposes of the instant invention saying that ethyl lactate and butyl lactate are the preferred alkyl lactates used in the invention.

It would have been obvious to one of ordinary skill in the art at the time of the invention to add the alkyl lactates of Lundberg to the composition of MVI-12 because of an expectation of further solubilizing the lipophilic constituents of MVI-12 and of providing an environmentally friendly and non-toxic composition. It is Examiner's

position that Lundberg teaches the functional equivalence of ethyl lactate and butyl lactate because (1) they have analogous structures and (2) they have similar physical properties and functions (pages 2-4). Accordingly, it would have been obvious to utilize butyl lactate in the MVI-12 composition because it is taught by Greff that ethyl lactate is useful for infusion of water-insoluble components and both Lundberg and Applicant teach that butyl lactate, an analogue of ethyl lactate, are functional equivalents of one another. One would have been motivated to add butyl lactate to the solution because of an expectation of similar success in preparing a composition capable of providing necessary vitamins to the recipient of such a composition. Furthermore, one would have been motivated to add the butyl lactate to the composition because an expectation of success in improving the solubility, and thereby the bioavailability, of the lipophilic components of the composition.

It would have been obvious to one of ordinary skill in the art at the time of the invention to teach the percentage weights of MVI-12 as that of the instant invention since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

It is Examiner's position that the flashpoint of a composition is a property of that composition. According, since it would have been obvious to combine butyl lactate with the composition of MVI-12, the flashpoint of that composition would have been obvious because a composition is inseparable from its properties.

It is Examiner's position that the recitation "a water-dispersible liquid vitamin food additive" is a recitation of an intended use of the composition claimed. Therefore, it is Examiner's position that the intended use is not considered a limitation and is of no significance to the claim construction because the claim is functionally complete without it. MPEP 2111.02.

Claims 74, 93, 98 and 99 are rejected under 35 U.S.C. 103(a) as being unpatentable over MVI-12 package insert, Lundberg, Greff and Applicant's admission as applied to claims 58-66, 68-73, 75-85, 87-92, 94-97, 100-101 and 105-107 above and further in view of Multi-12 (thinkPharm, June 2000, www.thinkpharm.com/pharma /preview/2000NDA/index.php?021163).

MVI-12 package insert, Lundberg, Greff and Applicant's admission apply as disclosed above. The references lack vitamin D3.

Multi-12 discloses a water-dispersible, substantial non-combustible and substantially flammable-alcohol/mono-hydroxy alcohol free liquid vitamin composition comprising vitamin A palmitate (vitamin A precursor oil), dl-alpha tocopheryl acetate (vitamin E precursor), cholecalciferol (vitamin D3), polysorbate 80 (emulsifier), and water.

It would have been obvious to one of ordinary skill in the art at the time of the invention to add the cholecalciferol (vitamin D3) of Multi-12 to MVI-12 because (1) MVI-12 and Multi-12 are both directed to multi-vitamin compositions for intravenous infusions; (2) MVI-12 and Multi-12 both teach ascorbic acid, vitamin A, thiamine, niacinamide, tocopheryl acetate, folic acid, biotin and cyanocobalamin as constituents of

their compositions; and (3) Multi-12 additionally teaches cholecalciferol (vitamin D3) as a constituent of their composition. Thus, one of skill in the art would have been motivated to add the cholecalciferol (vitamin D3) of Multi-12 to the composition of MVI-12 because of the expectation of providing a multi-vitamin that in addition to providing the physiological benefits associated with vitamins C, A, D, B1, B2, B6 and E, also provides the physiological benefits associated with vitamin D3.

Claims 67 and 86 are rejected under 35 U.S.C. 103(a) as being unpatentable over MVI-12 package insert, Lundberg, Greff and Applicant's admission as applied to claims 58-66, 68-73, 75-85, 87-92, 94-97, 100-101 and 105-107 above and further in view of Scialpi (USPN 4670247).

MVI-12 package insert, Lundberg, Greff and Applicant's admission apply as disclosed above. The references lack ethoxyquin.

Scialpi teaches a vitamin composition. Scialpi teaches that BHA, BHT or ethoxyquin may be used as antioxidants in such a composition (col. 2, lines 35-42). Accordingly, it is Examiner's interpretation that Scialpi teaches the equivalence of BHA, BHT and ethoxyquin as it pertains to vitamin compositions.

It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute ethoxyquin for BHT and/or BHA in the combined references because (1) it is considered prima facie obvious to substitute any known antioxidant, such as BHT or BHA, with another known antioxidant, absent evidence to the contrary; and (2) Scialpi teaches that BHA, BHT and ethoxyquin are each known to be useful in vitamin compositions. One would have been motivated by an expectation of achieving

a similar success by utilizing ethoxyquin as an antioxidant as had been achieved by using BHA and/or BHT.

Claims 102-104 and 108-113 are rejected under 35 U.S.C. 103(a) as being unpatentable over MVI-12 package insert, Lundberg, Greff and Applicant's admission as applied to claims 58-66, 68-73, 75-85, 87-92, 94-97, 100-101 and 105-107 above, and further in view of Boussouira et al. (USPN 6358514).

MVI-12 package insert, Lundberg, Greff and Applicant's admission apply as disclosed above. The references lack retinyl propionate.

Boussouira et al. teach retinol and retinyl propionate as combinable and interchangeable retinoids for use in bio-affecting compositions (col. 3, line 60-col.8, line 39).

It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute retinyl propionate for the retinol of MVI-12 because Boussouira et al. teach them as equivalent retinoids. One would have been motivated to make such a switch because of an expectation of similar success in providing vitamin A to a subject via a vitamin supplement composition.

Response to Arguments

In view of Applicant's amendments canceling all of the prior claims, the previous rejections have been withdrawn. The following is Examiner's consideration of Applicant's remarks as they pertain to the newly added claims.

With regard to the rejections of all of the claims under 35 U.S.C. 103(a) as they pertain to the M.V.I.-12 document, Applicant argues that "there is no evidence that the

M.V.I.-12 package insert was published prior to the filing date of the present application, which was August 3, 2001." Examiner does not find this argument persuasive, even as it applies to the newly used M.V.I.-12 reference of this office action. Examiner has now made of the record package inserts of M.V.I.-12 which were revised on 4/98, 7/99 and 11/00. Furthermore, Examiner provides extrinsic evidence of these documents as prior art in the form of Physicians Weekly (January 27, 1997, vol. XIV, No. 4, www.physweekly.com/archive/97/01_27_97/itn3.html). The article provides evidence that Astra USA's MVI-12 injection was available at least as early as January 27, 1997. Therefore, it is Examiner's position that since it is known that Astra USA's MVI-12 injection was publicly available prior to the revision of the package insert that the package insert of the 4/98 revision must have been made available to the public prior, at least, to the following, 7/99, revision. Accordingly, it is Examiner's position that the MVI-12 package insert dated 4/98 is, indeed, prior art.

Applicant further argues that "there is absolutely no teaching whatsoever in the package insert that the formulation would be suitable for oral administration," and that "the package insert teaches away from oral administration by warning that the product is suitable for intravenous infusion only." This argument is not persuasive because Applicant is not claiming a method of administering the composition but is claiming the composition itself. Patentable weight is not given to the preamble/intended use of the composition because the claims are functionally complete without any such limitation.

Applicant's arguments regarding the Lundberg reference are moot in view of Examiner's new rejections.

Applicant's arguments regarding the publication date of the Multi-12 package insert are rendered moot in view of the new rejections. Applicant's arguments that the Multi-12 reference, as applied to the new rejection, is not persuasive. Applicant argues against the Multi-12 reference, as against the MVI-12 reference above, because the "document is simply irrelevant to the animal food additive of the present claims." Again, it is Examiner's position that the claims are drawn to a composition and not a method of administration of that composition. Accordingly, weight is not given to the intended use of the composition.

Applicant's arguments regarding the Merck Index reference are rendered moot by the new rejections.

Applicant's argues that Boussouira et al. is "not relevant to the present invention or properly combinable with the formulations of the package inserts because they are topical formulations. Such formulations are not suitable for ingestion or intravenous infusion." These arguments are not persuasive. It is Examiner's position that Boussouira et al. is an analogous art because it pertains to the administration of vitamin A to a subject. Furthermore, Multi-12 teaches that an acylated retinol (vitamin A palmitate) is useful as a vitamin A source in intravenous injections. Accordingly, it would have been obvious to use an acylated retinol, namely retinyl propionate, instead of retinol because it is known that acylated retinols are useful in vitamin infusion compositions, as taught by Multi-12, and acylated retinoids, such as retinyl propionate, are known to behave in a similar biological function as retinol, as taught by Boussouira et al.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory W Mitchell whose telephone number is 571-272-2907. The examiner can normally be reached on M-F, 8 AM - 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

gwm

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